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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,300	01/23/2004	Zhaolin Wang	364-2US	4632

20212 7590 09/10/2004

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EXAMINER

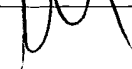
GRAVINI, STEPHEN MICHAEL

ART UNIT	PAPER NUMBER
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3749

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/762,300	Applicant(s) WANG ET AL. 	
	Examiner Stephen Gravini	Art Unit 3749	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) 1-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20040719</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Priority*

It is noted that this application appears to claim subject matter disclosed in unnamed prior Canadian application filed December 23, 2003. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C.

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119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on December 23, 2003. It is noted, however, that applicant has not filed a certified copy of the application as required by 35 U.S.C. 119(b).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by reference C1, cited by the applicants. That reference is considered to disclose the claimed invention comprising:

spraying a carrier liquid containing a powder forming ingredient to form a flow of liquid droplets (please see page 115 right column);

entraining the flow with a coolant for sufficient time to freeze the liquid droplets into frozen particles (please see page 115 right column); and

drying the frozen particles to form a dry powder (please see page 116 left column). Reference C1 is also considered to disclose a powder forming ingredient suspended or dissolved in a carrier liquid and a flow of liquid droplets entrained within a concurrent flow of coolant (see page 116 right column) and coolant temperature within a first temperature range during freezing of the liquid particles and a temperature warmer than the first temperature range during drying of the frozen particles (pages 116-117).

Claims 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Passey (US 3,909,957). Passey is considered to disclose the claimed invention comprising:

providing a flow of liquid droplets containing a powder forming ingredient to form a flow of liquid droplets (please see column 14 lines 28-45); and

treating the liquid droplets with a flow of coolant inside the chamber to freeze the liquid droplets prior to deposition and dry the deposited frozen particles, and thus form a powder and coolant concurrent with the flow of liquid droplets (please see column 22 lines 1-49). Passey is also considered to disclose flow of coolant for drying frozen

particles is in co-direction with the gravity as shown in figures 1 and 2 which show gravity flow prevention, and the flow of coolant prevents adherence of liquid droplets to walls of the chamber at column 13 lines 50-66, and liquid droplets containing more than one powder forming ingredient at column 6 lines 25-63.

Claims 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Soltani Ahmedi et al. (US 5,900,384). Soltani is considered to disclose the claimed invention comprising:

a chamber **7** having an atomizer **17** at one end of the chamber, the atomizer being connected to a source of the ingredient carrier liquid **9** (wherein the disclosed supply line is considered to anticipate the claimed carrier liquid because it carries liquid) to produce a flow of liquid droplets;

a nozzle system **15** for providing a flow of coolant that entrains atomized fluid sprayed by the atomizer;

a source of coolant **28** for the nozzle system; and  
a collector **23** spaced from the atomizer sufficiently that liquid droplets atomized by the atomizer are frozen by the flow of coolant before contact with the collector. Soltani is also considered to disclose the claimed nozzle system and atomizer are oriented to provide concurrent flows of coolant and liquid droplets as shown in figure 1, a ring nozzle at column 8 line 13 wherein the disclosed spinning disk atomizer is considered to anticipate the claimed ring nozzle because both are circularly oriented, the nozzle system is arranged around a porous wall defining a flow chamber through which the flow of liquid droplets passes at column 8 lines 16-30, a collector filter **25** at an exit from

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the chamber, and the atomizer and collector are at opposed ends of the chamber as shown in figure 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over reference C1 in view of Soltani. Reference C1 is considered to disclose the claimed invention, as discussed above under the anticipatory rejection, except for the claimed nozzle, chamber, filter collection, and more than one powder feature. Soltani is considered to disclose a nozzle, chamber, filter collection, and more than one powder feature at column 8 lines 1-54. It would have been obvious to one skilled in the art to combine the teachings of reference C1 with the teachings of a nozzle, chamber, filter collection, and more than one powder feature, considered disclosed by Soltani for the purpose of processing frozen particles subject to a lyophilization process.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gravini whose telephone number is 703 308 7570. The examiner can normally be reached on normal weekday business hours (east coast time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ira S. Lazarus can be reached on 703 308 1935. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

smg

September 8, 2004

*Stephen M. Gravini*